An Overview of Exposure Assessment, Emphasizing VCCEP

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This Presentation will…

- Describe the overall approach used by the U.S. EPA in assessing exposures
- Describe some exposure assessment issues that are particularly relevant for children's exposure assessment and VCCEP
- Provide some Internet resources and references which may be helpful

EPA's General Approach to Exposure Assessment -

1) Exposure can be *measured at the point of contact* while it is taking place (e.g., monitoring data)
2) Exposure can be *estimated using a scenario evaluation* which evaluates concentration and contact variables (e.g., predictive modeling)
3) Exposure can be *reconstructed using biomarkers* of exposure to estimate internal dose.

Reference: EPA Guidelines for Exposure Assessment

EPA Approaches for Evaluating Exposure Pathways and Scenarios

- An *exposure pathway* defines the course that a chemical takes from its source to the receptor's portal of entry (e.g., consumer product used indoors - inhalation)
- For any given exposure pathway, there are a set of associated exposure scenarios.
- An *exposure scenario* combines the source, population, timeframe, microenvironment, and macroactivity

EPA's Approaches for Characterizing Activity Patterns

- *Microenvironment*: specific description of place occupied during activity (e.g., indoors in the living room)
- *Macroactivity*: general description of what the child is doing (e.g., watching television)
- *Microactivity:* specific physical acts that are characteristic of the macroactivity (e.g., number of times the child touches the floor while watching television)

Exposure Assessment in a Risk Assessment Context

- Goal of exposure assessment for risk assessment purposes is often to estimate dose, which is combined with chemical-specific dose-response data to estimate risk
- Semi-quantitative approaches may be helpful for screening purposes
- Quantitative assessments generally require more data and information and are used for risk assessment purposes
- Exposure assessment is often conducted in an iterative manner, based on the purpose of the assessment
- For VCCEP, answering the question “have potential risks to children been adequately characterized” will determine the depth of the assessment needed

EPA's Approach to Using Predictive Models for Risk Assessment

- Selection of models must be carefully done to ensure that the model will meet the needs of the assessment (e.g., are potential risks to children adequately characterized)
- Representative monitoring data is preferred over models
- Screening level models can help to set priorities, identify where additional evaluation is needed
- Higher tier models provide more definitive, detailed analyses, often used in more advanced exposure assessments
- Models can be helpful in filling data gaps and to supplement data

Children's Exposure Assessment

- Children are not little adults
- Children eat and drink more for their size than adults
- Children play and act differently than adults
- Children's bodies are undergoing development
- Children may be less able to metabolize and excrete certain toxic substances

Reference: Michael Firestone, EPA, in EPA/630/R-00/005

Characteristics of Children that Influence Exposure

- Physiological characteristics
- Behavioral characteristics
  - Development (motor capacity, mouthing)
  - Physical activities
  - Diet and eating habits
- Other characteristics
  - Gender
  - Socioeconomic status
  - Race/ethnicity
- Exposure assessors need to understand the biological phenomena underlying age bins

Reference: Elaine A. Cohen Hubal, EPA, in EPA/630/R-00/005

Exposure in a Risk Assessment Context Using a Tiered Approach - VCCEP

- Preparation of Tier 1 assessment:
  - Hazard Assessment
  - Exposure Assessment
  - Risk Assessment
  - Tier 2 Data Needs Assessment
- For Tier 1, sponsors should develop a screening level assessment of readily available exposure information, including data on exposures outside the chain of commerce – put totality of exposures into context

VCCEP Exposure Assessments Should Include:

- All manufacturing and processing activities that can lead to potential exposures and releases which are relevant
- All industrial, commercial, and consumer uses leading to potential exposures and releases which are relevant
- Measures or estimates of environmental releases
- Physical chemical properties and environmental fate
- Activity patterns, age ranges and sub populations associated with activities

VCCEP Exposure Assessments Should Include, continued:

- Objective of the assessment (for each exposure estimate)
- Characterization of monitoring data, biomonitoring, and other studies used in the assessment
- Characterization of completeness of the assessment
- Transparency to enable reader to independently reach a conclusion
- Characterization of the quality of the data used and exposure estimates, including models

VCCEP Exposure Assessments Should Include, continued:

- Routes of exposure: inhalation, dermal, ingestion, ocular, in utero if applicable
- Amounts:
  - concentrations - e.g., ppm
  - potential dose rates - Lifetime Average Daily Dose (LADD; mg/kg/day), etc.
  - aggregate exposures
- Duration and frequencies (days/yr, yr/lifetime)
- Populations of relevance: children, prospective parents

VCCEP - Establish the Objective and Scope of the Assessment

- Objective – adequately characterize potential risks to children
- Scope of the assessment
  - Evaluate the VCCEP chemical for potential releases & relevant exposures during manufacture, processing, industrial use, commercial use, consumer use
  - Evaluate potential exposures occurring from sources which are outside the chain of commerce
  - Tier 1 is a screening level exposure assessment

First - Gather and Compile Readily Available Data and Information

- Company databases
- National databases (e.g., EPA, NHANES, NHEXAS, exposure factors databases, etc.)
- Studies published in the open literature
- References and other resources (e.g., for physical/chemical properties, fate, exposure factors, etc.)
- Obtain all relevant and needed supporting information
- Prepare ‘robust summaries’ for data

Second – Conduct a Screening Level Exposure Assessment

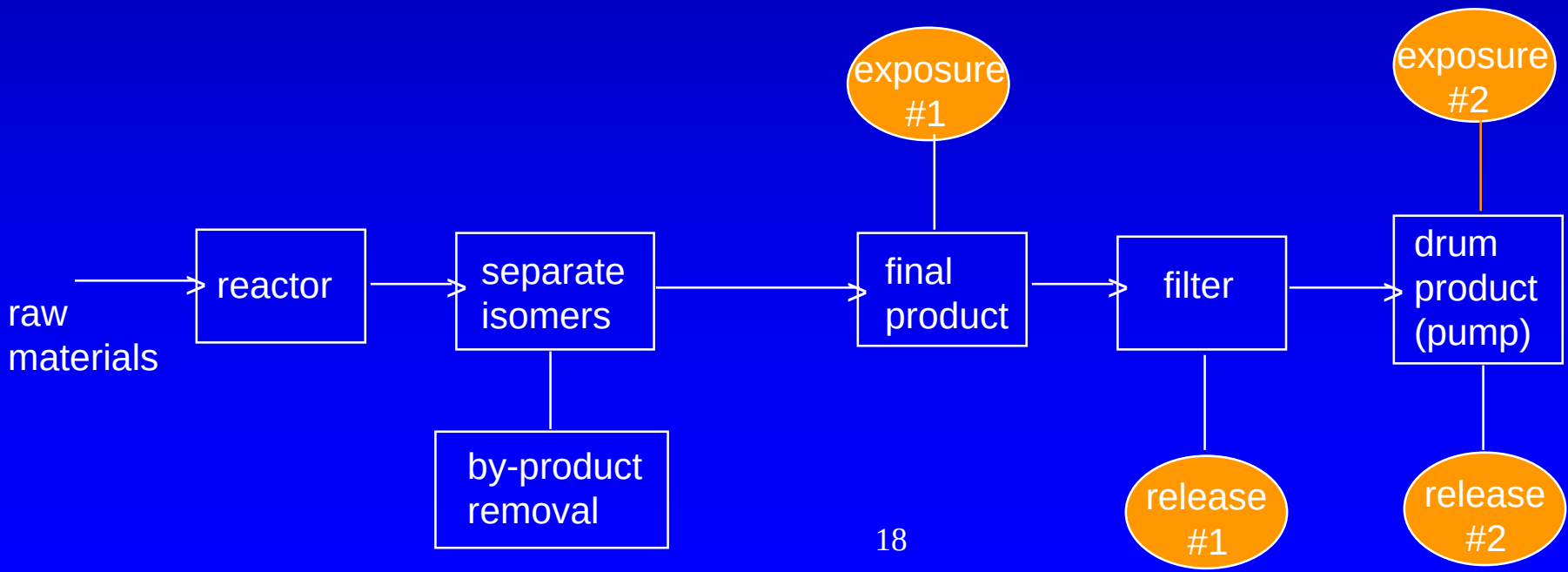
- Use readily available: measured data, existing release and exposure estimates, other exposure-related information
- Use a conservative (protective) approach in the exposure assessment
- Quantify exposures for use in screening level risk assessment

Screening Level Exposure Assessment, continued

- May use simple models to fill in gaps
- Screening models often use generic scenarios and assumptions
- Characterize the assessment, considering the quality of the data, completeness of the assessment, etc.
- Prepare the screening level exposure assessment and summary

Example Manufacturing Operation

- Process diagram – identify potential points of release and exposure



Example Children's Exposure Scenario

- Pathway – paint is source, children are receptors
- Scenario for children – watching television in the living room for XX hours while parent is painting in adjacent room; inhalation, dermal (carpet), etc.

Assessing Potential Exposures – Scenario Approach

- What is the assessment objective (conservative screening level, average, etc.)
- What is the source of the contaminant?
- Is the contaminant available when the exposure occurs?
- What is the population potentially exposed?
- What are the activity patterns, age ranges, behaviors, developmental attributes of children
- What are the potential exposures and potential dose rates for the population of interest?

Assessing Potential Exposures – Scenario Approach, continued

- What is the concentration, fate, and transport in the environment?
- What is the frequency, magnitude, and duration of exposure?
- What are the limitations, uncertainties, biases associated with the assessment?

Then, Advanced Exposure Assessment if Needed

- Focus on higher priority exposures identified in screening activities
- Estimate typical and high end human and environmental exposures
- A representative, comprehensive monitoring study of known quality is ideal
- A well designed monitoring study is generally more accurate than models
- May use higher tier models to fill in gaps
- For optimum results, higher tier models require accurate input data

Finalizing the Exposure Assessment

- Quantify exposure, including frequency and duration, address aggregate exposures, address biomonitoring data
- Characterize exposure for use in a risk assessment, addressing completeness, quality of the data and the exposure estimate, summarizing in a consistent and transparent manner
- Reporting in a consistent manner to enable a reader to easily find information when reviewing multiple summaries, and reach an independent conclusion

Reference: EPA's Risk Characterization Handbook

VCCEP - What's Smart

- Determine whether a more thorough evaluation of exposure is suggested, even at Tier 1, based on presence in human tissues, availability of higher tier toxicological data, or other information
- Provide a basis for 'bold' statements included in the assessment and/or summary

Some Internet Resources for Exposure Assessment

- EPA National Center for Environmental Assessment (NCEA): http://www.epa.gov/ncea/document.htm
- EPA/NCEA Risk Assessment Forum: http://www.epa.gov/ncea/raf/
- EPA OPPT Exposure Assessment: http://www.epa.gov/oppt/exposure
- EPA pesticide info and OPP: http://epa.gov/pesticides/
- EPA OPP science policy and guidance: http://www.epa.gov/oppfead1/trac/science/
- Alliance for Chemical Awareness: http://www.chemicalawareness.org/toolkit/library.html